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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/039,957	03/16/1998	PAUL L. KORNBLITH	2509-970451	1251

7590

04/14/2003

BARBARA E JOHNSON
WEBB ZIESENHEIM BRUENING LOGSDON
ORKIN & HANSON 700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 152191818

EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/039,957

Applicant(s)
Kornblith

Examiner
Ralph Gitomer

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 17, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-47 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 38 6) ☐ Other: _____

The RCE request and IDS received 10/17/2002 have been entered and claims 40-47 are currently pending in this application. Please inform the examiner of all related cases, allowed, abandoned or pending. This application is a CIP, please inform the examiner as to how this application differs from any previous applications to determine the proper priority date. Priority is granted to 3/16/1998 at this time.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kornblith.

Kornblith (J Neurosurg) entitled ~~✕~~Variations in Response of Human Brain Tumors to BCNU in vitro~~✕~~ teaches on page 580 column 2, malignant biopsy tissue was minced into 1 cubic millimeter pieces and grown into monolayers. On page 581 column 1 the cells are plated into 60 well plates. On page 585 column 1, the cytotoxic effects may include alterations to the cells that render them incapable of adhering to a surface or actual cell

death. Further studies are necessary to determine more precisely what toxic effects BCNU has on cells.

All the features of the claims are taught by Kornblith for the same function as claimed.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be

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negated by the manner in which the invention was made.

Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornblith.

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Kornblith (J Neurosurg) entitled ~~✕~~Variations in Response of Human Brain Tumors to BCNU in vitro~~✕~~ teaches on page 580 column 2, malignant biopsy tissue was minced into 1 cubic millimeter pieces and grown into monolayers. On page 581 column 1 the cells are plated into 60 well plates. On page 585 column 1, the cytotoxic effects may include alterations to the cells that

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render them incapable of adhering to a surface or actual cell death. Further studies are necessary to determine more precisely what toxic effects BCNU has on cells.

The claims differ from Kornblith in that they specify the type of agent, and the type of factors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to test any known cytotoxic compounds for their known effects in view of Kornblith who tests a known chemotherapeutic agent. Kornblith counts
5 intact cells after incubating with the agent to determine the effect of the agent upon the condition of the cells. Claims 46 and 47 determine a change in secreted factors which would be expected to reflect the condition of the cells. See the present specification last paragraph page 3 bridging to page 4.


10 The following prior art pertinent to applicant's disclosure is made of record and not relied upon:
Kornblith (5,728,541 and 6,416,967) are related cases.
Kornblith (Clin Neurosurgery) entitled ~~✕~~Role of Tissue Culture in
15 Prediction of Malignancy~~✕~~ teaches on page 347 last paragraph bridging to page 348, fragments are minced to a size of less than 1 cubic millimeter and gown into a monolayer in multiple cells to determine the chemical sensitivity to various agents.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If
25 attempts to reach the examiner by telephone are unsuccessful, the

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examiner's supervisor, Michael Wityshyn can be reached on (703)
308-4743. The fax phone number for this Art Unit is (703) 308-
4556. Any inquiry of a general nature or relating to the status
of this application should be directed to the Group receptionist
whose telephone number is (703) 308-1235. For 24 hour access to
patent application information 7 days per week, or for filing
applications electronically, please visit our website at
www.uspto.gov and click on the button Patent Electronic Business
Center for more information.



Ralph Gitomer
Primary Examiner
Group 1651

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200